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# Advisory Committee on Immunization Practices Votes to Recommend Routine Use of Pfizer's PREVNAR 20™ (Pneumococcal 20-valent Conjugate Vaccine) in Adults

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- *One dose of PREVNAR 20 is recommended by ACIP for adults ages 65 and older and adults ages 19 to 64 with certain risk conditions*
- *New PREVNAR 20 one-dose guidance helps simplify long-standing adult pneumococcal recommendations*

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE:PFE) announced today that the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) voted to recommend PREVNAR 20™ (Pneumococcal 20-valent Conjugate Vaccine) for routine use to help protect adults against invasive disease and pneumonia caused by the 20 *Streptococcus pneumoniae* (pneumococcus) serotypes in the vaccine. Specifically, the ACIP voted to recommend the following:

- *Adults 65 years of age or older who have not previously received a pneumococcal conjugate vaccine or whose previous vaccination history is unknown should receive a pneumococcal conjugate vaccine (either PCV20 or PCV15). If PCV15 is used, this should be followed by a dose of PPSV23.*
- *Adults aged 19 years of age or older with certain underlying medical conditions or other risk factors[1] who have not previously received a pneumococcal conjugate vaccine or whose previous vaccination history is unknown should receive a pneumococcal conjugate vaccine (either PCV20 or PCV15). If PCV15 is used, this should be followed by a dose of PPSV23.*

The recommendations will be forwarded to the director of the CDC and the U.S. Department of Health and Human Services for review and following approval, the recommendations are published in the *Morbidity and Mortality Weekly Report*. This will represent the first-time any pneumococcal conjugate vaccine has been routinely recommended for certain risk populations ages 19 to 64 years, such as people with diabetes and asthma.

"A single dose of PREVNAR 20 helps protect adults against vaccine-type pneumococcal pneumonia and invasive pneumococcal disease during a period where their risk is gradually increasing due to aging among other factors. Today's vote acknowledges the important role of adult immunizations in helping protect eligible populations against certain potentially serious respiratory diseases during the current pandemic and beyond," said Luis Jodar, Ph.D., Senior Vice President and Chief Medical Officer, Pfizer Vaccines. "The ACIP recommendation recognizes the significance as well of helping protect more populations under age 65 with co-morbid and immunocompromising conditions who are at increased risk of disease against these 20 disease-causing serotypes."

The seven additional serotypes in PREVNAR 20 represent 30 percent of overall of invasive pneumococcal disease burden in U.S. adults.[2] Pneumococcal pneumonia results in more than 180,000 adult hospital admissions and more than 150,000 adult outpatient visits in the U.S. each year.[3]

“The new simplified ACIP recommendation may offer the opportunity to improve immunization rates and therefore help prevent more disease,” said Nanette Cocero, Ph.D., Global President, Pfizer Vaccines. “We believe that as U.S. health care professionals start implementing this ACIP recommendation, once endorsed by the CDC Director, PREVNAR 20 recommended as a single dose has the potential to provide an important public health benefit for adults. Building on Pfizer’s more than 20-year legacy of developing and supplying pneumococcal conjugate vaccines, we remain committed to working with the healthcare and public health communities to raise awareness of the importance of adult immunization and encourage recommended individuals to get vaccinated.”

**About PREVNAR 20**

PREVNAR 20 is a next-generation pneumococcal conjugate vaccine that includes capsular polysaccharide conjugates for the 13 serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F) already included in Prevnar 13® (Pneumococcal 13-valent Conjugate Vaccine [Diphtheria $CRM_{197}$ Protein]). The vaccine also contains capsular polysaccharide conjugates for seven additional serotypes (8, 10A, 11A, 12F, 15B, 22F and 33F) that cause invasive pneumococcal disease (IPD),[4,5,6,7,8] and have been associated with high case-fatality rates,[9,10,11,12] antibiotic resistance,[13,14,15] and/or meningitis.[16,17] PREVNAR 20 contains the broadest serotype coverage of any conjugate vaccine available; and helps protect against more strains of the bacteria that cause pneumococcal pneumonia than any conjugate vaccine available.

On June 8, 2021, Pfizer announced the U.S. Food and Drug Administration (FDA) approved PREVNAR 20 for the prevention of invasive disease and pneumonia in adults age 18 years or older. On February 26, 2021, the European Medicines Agency (EMA) accepted for review Pfizer’s Marketing Authorization Application (MAA) for the 20-valent pneumococcal conjugate vaccine candidate, as submitted for the prevention of invasive disease and pneumonia caused by *S. pneumoniae* serotypes in the vaccine in adults ages 18 years and older. The formal review process by the EMA’s Committee for Medicinal Products for Human Use (CHMP) currently is ongoing.

**INDICATIONS FOR PREVNAR 20™**

- PREVNAR 20™ is a vaccine indicated for active immunization for the prevention of pneumonia and invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F in adults 18 years of age and older
- This indication for the prevention of pneumonia caused by *S. pneumoniae* serotypes 8, 10A, 11A, 12F, 15B, 22F, and 33F is approved under accelerated approval based on immune responses as measured by opsonophagocytic activity (OPA) assay. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

**U.S. IMPORTANT SAFETY INFORMATION**

- PREVNAR 20™ should not be given to anyone with a history of severe allergic reaction to any component of PREVNAR 20™ or any diphtheria toxoid–containing vaccine
- Some adults with weakened immune systems may have a lower response to PREVNAR 20™. Safety data are not available for these groups. Your healthcare provider can tell you if PREVNAR 20™ is right for you
- In adults 18 years of age and older, the most common side effects were pain at the injection site, muscle pain, fatigue, and headache

- Ask your healthcare provider about the risks and benefits of PREVNAR 20™. Only a healthcare provider can decide if PREVNAR 20™ is right for you

Please see full prescribing information for PREVNAR 20™.

**About Pfizer: Breakthroughs That Change Patients' Lives**

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 170 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.Pfizer.com. In addition, to learn more, please visit us on www.Pfizer.com and follow us on Twitter at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

***DISCLOSURE NOTICE:***

*The information contained in this release is as of October 20, 2021. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.*

*This release contains forward-looking information about PREVNAR 20™ (Pneumococcal 20-valent Conjugate Vaccine [Diphtheria CRM197 Protein]), including its potential benefits and a recommendation by ACIP for routine use to help protect adults in the U.S. against invasive disease and pneumonia caused by the 20 Streptococcus pneumoniae (pneumococcus) serotypes in the vaccine, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, uncertainties regarding the commercial success of PREVNAR 20 and uncertainties regarding the commercial impact of ACIP's recommendation; the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when any biologics license applications may be filed in any other jurisdictions for PREVNAR 20 for the prevention of invasive disease and pneumonia in adults age 18 years or older and in any jurisdictions for any other potential indications; whether and when the MAA pending in the EU may be approved and whether and when any such other applications that may be pending or filed may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether PREVNAR 20 will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of PREVNAR 20; uncertainties regarding the ability to obtain recommendations from vaccine advisory or technical committees and other public health authorities regarding PREVNAR 20 and uncertainties regarding the commercial impact of any such recommendations; the impact of COVID-19 on our business, operations and financial results; and competitive developments.*

*A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2020 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.*

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[1] Alcoholism, chronic heart/liver/lung disease, cigarette smoking, diabetes mellitus, chronic renal failure, nephrotic syndrome, immunodeficiency, iatrogenic immunosuppression, generalized malignancy, human immunodeficiency virus, Hodgkin disease, leukemia, lymphoma, multiple myeloma, solid organ transplants, congenital or acquired asplenia, sickle cell disease or other hemoglobinopathies, CSF leak, or cochlear implant.

[2] Gierke R, Advisory Committee on Immunization Practices (ACIP). Current Epidemiology of Pneumococcal Disease and Pneumococcal Vaccine Coverage among Adults, United States. Centers for Disease Control and Prevention (CDC). February 25, 2021. https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-02/24-25/02-Pneumococcal-Gierke.pdf.

[3] Data on file. Pfizer Inc., New York, NY

[4] Baisells E, Guillot L, Nair H, et al. Serotype distribution of Streptococcus pneumoniae causing invasive disease in children in the post-PCV era: A systematic review and meta-analysis. PlosOne. 2017;12(5): e0177113.

[5] Hausdorff W & Hanage W. Interim results of an ecological experiment – Conjugate Vaccination against the pneumococcus and serotype replacement. Hum Vaccin Immunother. 2016;12(2):358-374.

[6] Cohen R, Cohen J, Chalumeau M, et al. Impact of pneumococcal conjugate vaccines for children in high- and non-high income countries. Expert Rev Vaccines. 2017;16(6):625-640.

[7] Moore M, Link-Gelles R, Schaffner W, et al. Effect of use of 13-valent pneumococcal conjugate vaccine in children on invasive pneumococcal disease in children and adults in the USA: analysis of multisite, population-based surveillance. Lancet Infect Dis. 2015;15(3):301-309.

[8] Metcalf B, Gertz RE, Gladstone RA, et al. Strain features and distributions in pneumococci from children with invasive disease before and after 13-valent conjugate vaccine implementation in the USA. Clin Microbiol Infect. 2016;22(1):60. e9-60. e29.

[9] Oligbu G, Collins S, Sheppard CL, et al. Childhood Deaths Attributable to Invasive Pneumococcal Disease in England and Wales, 2006–2014. Clin Infect Dis. 2017;65(2):308-314.

[10] van Hoek, Andrews N, Waight PA, et al. Effect of Serotype on Focus and Mortality of Invasive Pneumococcal Disease: Coverage of Different Vaccines and Insight into Non-Vaccine Serotypes. PlosOne. 2012;7(7: e39150.

[11] Stanek R, Norton N, Mufson M. A 32-Years Study of the Impact of Pneumococcal Vaccines on Invasive Streptococcus pneumoniae Disease. Am J Med Sci. 2016;352(6):563-573.

[12] Harboe ZB, Thomsen RW, Riis A, et al. Pneumococcal Serotypes and Mortality following Invasive Pneumococcal Disease: A Population-Based Cohort Study. PlosOne. 2009;6(5): e 1000081.

[13] Azzari C, Cortimiglia M, Nieddu F, et al. Pneumococcal serotype distribution in adults with invasive disease and in carrier children in Italy: Should we expect herd protection of adults through infants' vaccination? Hum Vaccin Immunother. 2016;12(2):344-350.

[14] Tomczyk S, Lynfield R, Schaffner W, et al. Prevention of Antibiotic-Nonsusceptible Invasive Pneumococcal Disease With the 13-Valent Pneumococcal Conjugate Vaccine. Clin Infect Dis. 2016;62(9):1119-1125.

[15] Mendes RE, Hollingsworth RC, Costello A, et al. Noninvasive Streptococcus pneumoniae Serotypes Recovered from Hospitalized Adult Patients in the United States in 2009 to 2012. Antimicrob Agents Chemother. 2015;59(9):5595-5601.

[16] Olarte L, Barson WJ, Lin PL, et al. Impact of the 13-valent pneumococcal conjugate vaccine on pneumococcal meningitis in US children. Clin Infect Dis. 2015;61(5):767-775.

[17] Thigpen MC, Whitney CG, Messonnier NE, et al. Bacterial Meningitis in the United States, 1998–2007. NEJM. 2011;364(21):2016-2025.

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